UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
OFFICE OF RESEARCH AND DEVELOPMENT
RESEARCH TRIANGLE PARK, NC 27711

January 13, 2010

MEMORANDUM

SUBJECT: IRB Study # 09-1625: Epigenetic Effects of Diesel exhaust and Ozone Exposure

FROM: Melanie J. Jardim, Ph.D.
Environmental Public Human Division

TO: R. Julian Preston, Ph.D., Associate Director for Health NHEERL

A portion of the population is known to be more sensitive to the exposure of air pollutants, such as diesel exhaust and ozone, which may be due to underlying epigenetic mechanisms. Similar to the DNA sequence, control of gene expression, epigenetics, can be inherited from generation to generation. No one has yet studied if diesel exhaust and ozone exposure can induce changes in epigenetic mechanisms in individuals, or whether certain pre-existing patterns within the epigenome can be used as biomarkers for susceptibility. In this study, we will assess whether biological responses associated with short-term exposure to diesel exhaust or ozone can be attributed to changes in epigenetics and whether epigenetic marks can be used to identify susceptibility to these pollutants.

This is a request for review and approval of human study research protocol #09-1625. Within this packet, I have submitted the following documents

- Cover memo
- NHEERL sign-off sheet with signatures
- NHEERL Fact Sheet
- NHEERL Study Justification Document
- IRB approval letter
- Research protocol as approved by the IRB
- Consent forms approved and stamped by the IRB
- Questionnaires and advertising approved and stamped by the IRB
- Ethics training reports required by the IRB
- Copies of extramural scientific reviews and responses